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The time period for reply, if any, is set in the attached communication.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

*Ex parte MIKA JOKINEN, TIMO PELTOLA, SINIKKA VEITTOLA,
MANJA AHOLA, and PIRJO KORTESUO*

Appeal 2010-005122
Application 09/913,643
Technology Center 1600

Before ERIC GRIMES, LORA M. GREEN, and
MELANIE L. McCOLLUM, *Administrative Patent Judges*.

GREEN, *Administrative Patent Judge*.

DECISION ON APPEAL¹

This is a decision on appeal under 35 U.S.C. § 134 from the
Examiner's rejection of claims 24-33. (App. Br. 1.)

¹ The two-month time period for filing an appeal or commencing a civil action, as recited in 37 C.F.R. § 1.304, or for filing a request for rehearing, as recited in 37 C.F.R. § 41.52, begins to run from the "MAIL DATE" (paper delivery mode) or the "NOTIFICATION DATE" (electronic delivery mode) shown on the PTOL-90A cover letter attached to this decision.

We have jurisdiction under 35 U.S.C. § 6(b).

STATEMENT OF THE CASE

Claims 30 and 32 are the independent claims on appeal, and read as follows:

30. A biodegradable silica fibre spun from silica sol, a biodegradation rate of said fibre being adjusted by controlling the starting point of the spinning process by a viscosity of the silica sol wherefrom the fibre is spun, said fibre having a solubility rate in simulated body fluid of 0.2 to 20 wt-%/h.

32. A biodegradable silica fibre spun from a silica sol, a biodegradation rate of the fibre being adjusted by controlling the viscosity of the spinning sol wherefrom the fibre is spun, said fibre having a solubility rate in simulated body fluid of 0.2 to 20 wt-%/h.

The claims are subject to the following grounds of rejection:

- I. Claims 24-33 stand rejected under 35 U.S.C. § 103(a) as being rendered obvious by Ahola.²
- II. Claims 24-33 stand rejected under 35 U.S.C. § 103(a) as being rendered obvious by Glaubitt.³

We reverse.

PRINCIPLES OF LAW

We recognize that during prosecution before the Office, claims are to be given their broadest reasonable interpretation consistent with the Specification as it would be interpreted by one of ordinary skill in the art. *In*

² Ahola, WO 97/45367, published Dec. 4, 1997.

³ Glaubitt, DE 196 09 551 published Oct. 19, 2001 (English translation).

re American Academy Of Science Tech Center, 367 F.3d 1359, 1364 (Fed. Cir. 2004). Claim language, however, “should not [be] treated as meaningless.” *Bicon, Inc. v. Straumann Co.*, 441 F.3d 945, 951 (Fed. Cir. 2006). Moreover, “the claims themselves provide substantial guidance as to the meaning of particular claim terms.” *Philips v. AWH Corp.*, 415 F.3d 1303, 1314 (Fed. Cir. 2005) (en banc).

While the analysis under 35 U.S.C. § 103 allows flexibility in determining whether a claimed invention would have been obvious, *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007), it still requires showing that “there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue.” *Id.* “We must still be careful not to allow hindsight reconstruction of references to reach the claimed invention without any explanation as to how or why the references would be combined to produce the claimed invention.” *Innogenetics, N.V. v. Abbott Labs.*, 512 F.3d 1363, 1374 n.3 (Fed. Cir. 2008). Moreover, the Examiner must consider all of the claim limitations in setting forth a rejection over the prior art. *See, e.g., In re Geerdes*, 491 F.2d 1260, 1262-63 (CCPA 1974) (in considering grounds of rejection, “every limitation in the claim must be given effect rather than considering one in isolation from the others.”).

CLAIM INTERPRETATION

In order to give meaningful weight to the claim limitation that the biodegradable silica fibers have “a solubility rate in simulated body fluid of 0.2 to 20 wt-%/h,” we interpret that limitation as requiring that the average solubility rate upon complete dissolution of the fiber be between 0.2 to 20

wt-%/h. Given that interpretation, at the slowest solubility rate of 0.2 wt-%/h, the fiber will have completely dissolved in approximately 21 days.⁴ (See FF10, set forth below.)

ISSUE (Ahola)

Has the Examiner established by a preponderance of the evidence that Ahola renders the biodegradable silica fiber of independent claims 30 and 32 having a solubility rate in simulated body fluid of 0.2 to 20 wt-%/h obvious?

FINDINGS OF FACT

FF1 According to the Specification, “the present invention is directed to methods for preparing controllably biodegradable silica fibres comprising spinning the fibres from a silica sol, the viscosity of the sol being controlled.” (Spec. 1.)

FF2 According to the Specification, “the biodegradation of the silica fibres can be controlled by controlling the viscosity of the spinning solution and, thus, the biodegradation of the silica fibres can be varied even when the same recipe is used.” (Spec. 2.)

FF3 The Examiner’s statement of the rejection may be found at pages 5-6 of the Examiner’s Answer.

FF4 Specifically, the Examiner finds that “Ahola discloses controllably biodegradable silica-xerogel fibers prepared via a sol-gel process.” (Ans. 5.)

⁴ At a dissolution rate of 0.2 wt%/hr, in order to obtain 100 % dissolution, it would take approximately 500 hours (100/0.2), or 20.8 days.

FF5 The Examiner finds further that an “in vivo dissolution test conducted on rats by implanting silica fibers showed that the fibers ha[d] been integrated into the surrounding connective tissues after two weeks of the implantation.” (*Id.* at 6 (citing Ahola, pp. 14-15).)

FF6 In the in vivo rat implantation experiment of Ahola, Ahola implanted silica xerogel fibres subcutaneously in rats, and the rats were killed two weeks after implanatation. (Ahola, pp. 14-15.)

FF7 According to Ahola:

In histological sections, toluidine blue stained the surroundings of the fibers blue, possibly because of the dissolved silica from the fibers. Almost all fibers had integrated well into the surrounding connective tissue. No signs of resorption of the fibers could be observed in SEM examination. No Ca,P-layer could be observed on the surface of the fibers.

(*Id.* at 15.)

FF8 We note further that Ahola teaches that “[s]ilica-xerogel fibers produced by a glass rod spinneret technique and kept in an exiccator for four months produced materials that dissolved 2.5 w-% per week.” (*Id.* at 9.)

FF9 The Examiner notes that “Ahola does not disclose the claimed dissolution rate of 0.2 to 20 wt%/h.” (Ans. 6.) The Examiner concludes, however, that the ordinary artisan could determine the dissolution rate of the fiber implanted in the rat, and that “[i]n the absence of factual evidence, the claimed dissolution rate is not patentable over the prior art fiber that dissolves after 2 weeks of implantation.” (*Id.*)

FF10 The Declaration of Mika Jokinen (Jokinen Declaration),⁵ states that the “0.2 to 20 wt-%/h solubility rate range of the claimed fiber means it dissolves very quickly in simulated body fluid – at the slowest solubility rate of 0.2 wt-%/hour, the claimed fiber will dissolve completely within 21 days.” (Jokinen Declaration, ¶4.)

ANALYSIS

Appellants argue that the *in vivo* example of Ahola performed in rats refers to integration, and not dissolution, thus the fibers did not dissolve within the two weeks, but were integrated (mixed) with the surrounding connective tissue. (App. Br. 11.) Appellants also assert that the solubility rate expressly taught by Ahola of 10 wt-% within four weeks (2.5 wt-% per week (FF8)), corresponds to a solubility rate of 0.0148 wt-%/hr, which is well below the claimed minimum solubility rate of 0.20 wt-%/hr. (*Id.* at 7.)

We agree with Appellants that the Examiner has not established that Ahola renders obvious the independent claims 30 and 32, drawn to a biodegradable silica fiber “having a solubility rate in simulated body fluid of 0.2 to 20 wt-%/h.” As noted by Appellants, the one solubility rate disclosed by Ahola of 10 wt-% within four weeks (2.5 wt-% per week (FF8)), which corresponds to a solubility rate of 0.0148 wt-%/hr, is well below the claimed minimum solubility rate of 0.20 wt-%/hr. Moreover, as to the *in vivo* example of the fibers of Ahola being implanted in rats, as taught by Ahola, the fibers had been “had integrated well into the surrounding connective

⁵ Declaration under 37 C.F.R. § 1.132 of Mika Jokinen, executed June 12, 2007.

tissue” and that “[n]o Ca,P-layer could be observed on the surface of the fibers” (FF7), thus the fibers were still present in the rat, and had not dissolved.

In addition, the Examiner has provided no reason as to why the ordinary artisan would have wanted to modify the fibers of Ahola such that they have the solubility rate set forth by independent claims 30 and 32. Nor has the Examiner provided any evidence or reasoning as to how a fiber having that solubility rate would be obtained using the methods of Ahola. We are thus compelled to reverse the rejection.

CONCLUSION OF LAW

We conclude that the Examiner has not established by a preponderance of the evidence that Ahola renders the biodegradable silica fiber of independent claims 30 and 32 having a solubility rate in simulated body fluid of 0.2 to 20 wt-%/h obvious. We are thus compelled to reverse the obviousness rejection of claims 24-33 over Ahola.

ISSUE (Glaubitt)

Has the Examiner established by a preponderance of the evidence that Glaubitt renders the biodegradable silica fiber of independent claims 30 and 32 having a solubility rate in simulated body fluid of 0.2 to 20 wt-%/h obvious?

FINDINGS OF FACT

FF11 The Examiner's statement of the rejection may be found at pages 7-8 of the Answer.

FF12 The Examiner finds that Glaubitt discloses biodegradable silica fibers spun from silica sol. (Ans. 7.)

FF13 The Examiner finds further that Glaubitt teaches "that the fiber dissolves/degrades at 10-100nm fiber radius per day and a fiber having a radius of 10 μ m completely dissolves in 50-500 days. (*Id.* (citing Glaubitt, p. 4).)

FF14 The Examiner concludes:

The prior art discusses dissolution in terms of radius of the fiber/day. The claimed invention discusses dissolution in terms of wt%/hr. The radius of fiber/day dissolved can be converted to radius of fiber/hr by the person of ordinary skill or the skilled artisan. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was [made] to prepare silica fiber according to [Glaubitt]. One having ordinary skill in the art would be motivated to prepare the fiber of [Glaubitt] with the expectation that a fiber having a radius of 10 mm would dissolve/degrade within 50-500 days. One having ordinary skill in the art would have the technical know how to determine the degradation/dissolution rate in wt%/day or wt%/h and to adjust the degradation rate according to the desired use as suggested by [Glaubitt]. In the absence of factual evidence the claimed dissolution rate does not patentably distinguish the fiber of the prior art having dissolution rate in radius/day, which can be converted to radius/h.

(Ans. 7-8.)

ANALYSIS

Appellants argue that Glaubitt teaches a fiber having a 10 micron diameter will be completely degraded within 50 to 500 days. (App. Br. 18.) According to Appellants, in contrast, “the claimed fiber will completely dissolve in about 21 days at its slowest solubility rate.” (*Id.*)

We agree with Appellants that the Examiner has not established that Glaubitt renders obvious the independent claims 30 and 32. As noted by Appellants, Glaubitt teaches that its fibers dissolve completely within 50 to 500 days, which is well above the 21 days in which the claimed fiber will dissolve.

In addition, the Examiner has provided no reason as to why the ordinary artisan would have wanted to modify the fibers of Glaubitt such that they have the solubility rate set forth by independent claims 30 and 32. Nor has the Examiner provided any evidence or reasoning as to how a fiber having that solubility rate would be obtained using the methods of Glaubitt. We are thus compelled to reverse the rejection.

Appeal 2010-005122
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CONCLUSION OF LAW

We conclude that the Examiner has not established by a preponderance of the evidence that Glaubitt renders the biodegradable silica fiber of independent claims 30 and 32 having a solubility rate in simulated body fluid of 0.2 to 20 wt-%/h obvious. We are thus compelled to reverse the obviousness rejection of claims 24-33 over Glaubitt.

REVERSED

alw

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